JAN - 4 2001

K00 3498

# Fresenius Medical Care

## Fresenius Optiflux 200A Hemodialyzer
## "Special" 510(k) Premarket Notification
## Summary of Safety and Effectiveness

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This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

**A. Submitter's Information:**

| | |
|---|---|
| Name: | Fresenius Medical Care North America |
| Address: | 95 Hayden Ave<br>Two Ledgemont Center<br>Lexington, MA 02420 |
| Phone: | 1-781-402-9068 |
| Fax: | (781) 402-9082 |
| Contact Person: | Arthur Eilinsfeld, Director of Regulatory Affairs |
| Date of Preparation: | 8 November, 2000 |

**B. Device Name:**

| | |
|---|---|
| Trade Name: | Fresenius Optiflux 200A Hemodialyzer |
| Common/Usual Name: | Hemodialyzer |
| Classification Name: | Hemodialyzer, Re-use, High Flux |

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**C. Predicate Device Name:**

The Fresenius Optiflux 200A is a modified version of the Fresenius Hemoflow F80A, which was cleared under the following premarket notifications:

Hemoflow F80A

- #K861106 (4/7/86);
- #K870724 (4/1/87);
- #K926005 (8/23/94);
- #K970700 (9/15/98).

**D. Device Description/Indications for Use:**

The intended use for the Optiflux 200A is identical to that for the Fresenius F80A and is as follows:

***Intended Use***

*Optiflux 200A dialyzers are designed for acute and chronic hemodialysis and are appropriate for single and multiple use.*

**E. Substantial Equivalence:**

**1. Is the product a device?**

**YES** - The Fresenius Optiflux 200A is a device pursuant to 21 CFR §201 [321] (h).

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2. **Does the new device have the same intended use?**

   **YES** – The intended use for the Optiflux 200A is identical to that for the Fresenius F80A and is as follows:

   **Optiflux 200A - Intended Use**

   *Optiflux 200A dialyzers are designed for acute and chronic hemodialysis and are appropriate for single and multiple use.*

   **Fresenius Hemoflow F80A - Intended Use**

   *Hemoflow dialyzers are designed for acute and chronic hemodialysis and are appropriate for single and multiple use.*

3. **Does the device have technological characteristics that raise new types of safety or effectiveness questions?**

   **NO** – The Optiflux 200A is a modified version of the F80A with increased surface area. The technological characteristics of the Optiflux 200A are equivalent to those of the F80A and raise no new types of safety or effectiveness questions.

4. **Does descriptive or performance information demonstrate equivalence?**

   **YES** – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Optiflux 200A and demonstrates that it is substantially equivalent to the Fresenius F80A.

**F. Safety Summary**

The Optiflux 200A Hemodialyzer is substantially equivalent in construction, design, materials, and intended use to the commercially available Fresenius F80A dialyzer. In addition, testing of the Optiflux 200A indicates that the dialyzer is safe and effective for its intended use.

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## G. General Safety and Effectiveness Concerns

The Optiflux 200A labeling includes a package insert, which describes the device's indications for use, cautions and warnings that should be observed when using the device, as well as the general operating instructions. This information promotes safe and effective use of the dialyzer.

Arthur Eilinsfeld
Director of Regulatory Affairs

11/8/00
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Arthur Eilinsfeld
Director of Regulatory Affairs
Fresenius Medical Care North America
95 Hayden Avenue, Two Ledgemont Center
LEXINGTON, MA 02420

Re: K003498
Multiple-use Labeling for Fresenius Optiflux 200A Hemodialyzer
Dated: December 13, 2000
Received: December 15, 2000
Regulatory Class: II
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Eilinsfeld:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Fresenius Medical Care

**Fresenius Optiflux 200A Hemodialyzer**
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## Indications for Use Statement

**Device Name:**

Fresenius Optiflux 200A Hemodialyzer

**Indications for Use:**

Optiflux 200A dialyzers are designed for acute and chronic hemodialysis and are appropriate for single and multiple use.

**PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003498